DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 21, 2014

Aesculap Implant Systems, LLC
Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K143106
Trade/Device Name: VEGA Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: October 24, 2014
Received: October 29, 2014

Dear Ms. Tom Wing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K143106

Device Name
VEGA Knee System

Indications for Use *(Describe)*

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee System is designed for use with bone cement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

B. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

VEGA Knee System
October 24, 2014

COMPANY: Aesculap® Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

ESTABLISHMENT

REGISTRATION NUMBER: 3005673311

CONTACT: Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
Julie.TomWing@aesculap.com

DEVICE

TRADE NAME: VEGA Knee System

COMMON NAME: Total Knee System

DEVICE CLASS: CLASS II

PRODUCT CODE: JWH

REGULATION NUMBER: 888.3560

CLASSIFICATION NAME: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi constrained Cemented Prosthesis

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the addition of an uncoated CoCrMo version of the VEGA Knee System, 12mm and 14mm tibial extension stems, each with 12mm length and allowing interchangeability between existing cleared compatible components are substantially equivalent to the currently marketed Aesculap VEGA Knee System (K101281, K121879 and K140452) and Columbus PS Total Knee System (K030367).

DEVICE DESCRIPTION

VEGA Knee System is a semi-constrained cemented prosthesis with a posterior stabilized (PS) design. The femoral component, tibial plateau, extension stems and obturators are manufactured from Cobalt Chromium Molybdenum alloy (CoCrMo), with an optional Zirconium nitride (ZrN) coating. The tibial gliding surfaces (inserts) and patella are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The tibial plug is made of PEEK.

VEGA Knee System is made up of numerous components available in various sizes. The VEGA Knee System is compatible with Aesculap Columbus cruciate retaining/posterior stabilizing tibial plateaus (CR/PS and CRA/PSA) and augments.

All components are sterile and intended for single use only.

INDICATIONS FOR USE

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee System is designed for use with bone cement.

TECHNOLOGICAL CHARACTERISTICS

The option of an uncoated CoCrMo version of the VEGA Knee System, 12mm and 14mm tibial extension stems, each with 12mm length and interchangeability between existing cleared compatible components remain substantially equivalent to the currently marketed Aesculap VEGA Knee System and Columbus Total Knee System (K030367).

VEGA Knee System is currently marketed with a ZrN coating only. The alternate offering of an uncoated CoCrMo version shares the same design, same dimensions, same range of sizes and the same base materials as those offered in the current ZrN coated VEGA Knee system and similarly as that previously cleared in Columbus PS Total Knee System.

The new tibial extension stem share the same design, thread pattern and diameters as currently offered in Columbus and VEGA Knee Systems, only differing in length, 12mm. As those same thread patterns are shared between both Knee Systems, VEGA tibial extension stems may be used with Columbus tibial trays to further complement the existing compatibility previously cleared.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices -The Basic Elements" were done where applicable on the VEGA Knee System in support of a substantial equivalence determination. In addition,

- "Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi- Constrained Total Knee Prostheses"
- "Class II Special Controls Guidance Document for Knee Joint Patellofemorotibial & Femorotibial Metal/Polyer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA"
- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement"
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements"
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components"
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMPE) Used in Orthopedic Devices"

As a result of the risk analysis, a geometrical comparison was used to determine cross compatibility of VEGA tibial extension stems with Columbus CR/PS and CRA/PSA tibial trays. Results of the geometrical analysis demonstrated no risks of incompatibility related to thread dimensions, diameter and contact area between VEGA tibial extension stems and the intended tibial trays.